

Appl. No. 09/834,410
Amdt. dated August 15, 2003
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group

PATENT1 Amendments to the Claims:

2 This listing of claims will replace all prior versions, and listings, of claims in the application:

3 Listing of Claims:

4 1. (Currently amended) A timed-release compression-coated solid composition for oral
5 administration to a subject, said composition comprising:
6 a) a core tablet comprising a drug and a freely erodible filler, wherein said core
7 tablet ~~is capable of erodes~~ approximately 40% to approximately 90% erosion in the digestive
8 tract of said subject; and
9 b) an outer layer, ~~said outlayer~~ wherein said outer layer is made from a hydrogel-
10 forming polymer substance, and a hydrophilic base, wherein said outer layer optionally contains
11 a drug-hydrogel-forming polymer substance has a viscosity-average molecular weight of
12 2,000,000 or higher and/or a viscosity in an aqueous 1% solution (25° C) of 1,000 cp or higher,
13 and said hydrophilic base having solubility such that the amount of water needed to dissolve 1g
14 of said hydrophilic base is 5 mL or less; and
15 c) wherein the outer layer optionally contains another drug and the outer layer
16 essentially does not contain the same drug as the core tablet drug.

1 2. (Cancel)

1 3. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein there is approximately 75 wt% or less of said drug,
3 approximately 5 to approximately 80 wt% freely erodible filler, approximately 10 to
4 approximately 95 wt% hydrogel-forming polymer substance, and approximately 5 to
5 approximately 80 wt% hydrophilic base.

1 4. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more selected
3 from the group consisting of malic acid, citric acid, tartaric acid, polyethylene glycol, sucrose,
4 and lactulose.

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- 1 5. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more selected
3 from the group consisting of malic acid, citric acid and tartaric acid.
- 1 6. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the freely erodible filler for a basic drug is 1 or 2 or
3 more selected from the group consisting of malic acid, citric acid and tartaric acid.
- 1 7. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the freely erodible filler for an acidic or neutral
3 drug is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose or
4 lactulose.
- 1 8. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the hydrogel-forming polymer substance contains
3 at least one type of polyethylene oxide.
- 1 9. (Cancel)
- 1 10. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the core tablet contains hydrogel-forming polymer
3 substance.
- 1 11. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the hydrophilic base is 1 or 2 or more having
3 solubility such that the amount of water needed to dissolve 1 g base is 5 mL or less.
- 1 12. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 11, wherein the hydrophilic base is 1 or 2 or more selected
3 from the group consisting of polyethylene glycol, sucrose, and lactulose.

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1 13. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the hydrogel-forming polymer substance is at least
3 1 type of polyethylene oxide and further contains red ferric oxide and/or yellow ferric oxide.

1 14. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein a drug is brought to be effectively released or
3 absorbed in the lower digestive tract.

1 15. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein a drug is brought to be effective for
3 chronopharmacotherapy.

1 16. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein a drug is metabolized by cytochrome P-450.

1 17. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein a drug has the effect of inhibiting metabolism by
3 cytochrome P-450.

1 18. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 16, wherein the drug is metabolized by CYP3A4.

1 19. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 17, wherein the drug has the effect of inhibiting metabolism by
3 CYP3A4.

1 20. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the drug is 4'-[(2-methyl-1,4,5,6-
3 tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.

1 21. (Original) A method of timed release of a drug, whereby the composition in claim 1
2 is orally administered.

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1 22. (Original) A method for alleviating undesirable drug interaction between a drug and
2 other drugs used concomitantly that employ the same route for drug absorption, distribution,
3 metabolism or excretion *in vivo* in humans, whereby the composition in claim 1 is orally
4 administered.

1 23. (Original) A method of alleviating undesirable drug interaction with between a drug
2 having the effect of inhibiting drug metabolism *in vivo* in humans and another drug according to
3 claim 20 used concomitantly, whereby the composition in claim 1 is used.

1 24. (Original) In a hydrogel-forming compression-coated solid pharmaceutical
2 preparation comprising: a core tablet containing drug and outer layer made from hydrogel-
3 forming polymer substance and hydrophilic base, the improvement which comprises a timed-
4 release compression-coated solid composition according to claim 1.

1 25. (Original) In a hydrogel-forming compression-coated solid pharmaceutical
2 preparation comprising:
3 a core tablet containing drug and outer layer made from hydrogel-forming polymer
4 substance and hydrophilic base, the improvement which comprises a timed-release compression-
5 coated solid composition for oral administration, said composition comprising:
6 (1) a drug and freely erodible filler are mixed with the core tablet;
7 (2) the percentage erosion of the core tablet is approximately 40 to approximately 90%;
8 and
9 (3) the outer layer essentially does not contain the same drug as the above-mentioned
10 drug.

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26. (Original) The timed-release compression-coated solid composition for oral administration according to claim 25, wherein the drug is 4'-[(2-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.